

Jeffrey M. Singletary, Bar No. 233528
jsingletary@swlaw.com
Justin F. Mello, Bar No. 329514
jmello@swlaw.com
SNELL & WILMER L.L.P.
600 Anton Blvd, Suite 1400
Costa Mesa, California 92626-7689
Telephone: 714.427.7000
Facsimile: 714.427.7799

Attorneys for Non-Party
ALLIANCE HEALTHCARE PARTNERS LLC

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

SURGICAL INSTRUMENT SERVICE
COMPANY, INC.,

Plaintiff/
Counterclaim-Defendant

vs.

INTUITIVE SURGICAL, INC.,

Defendant/
Counterclaim-Plaintiff.

Lead Case No. 3:21-CV-03496-VC
Hon. Vince Chhabria
Dept. 5

**DECLARATION OF JEFFREY L.
BERHOLD IN RESPONSE TO
DEFENDANT INTUITIVE
SURGICAL, INC.'S MOTION TO
CONSIDER WHETHER
ANOTHER PARTY'S
MATERIAL SHOULD BE
SEALED PURSUANT TO CIVIL
LOCAL RULE 79-5(f)**

SNELL & WILMER
LLP

LAW OFFICES
600 ANTON BLVD, SUITE 1400
COSTA MESA, CALIFORNIA 92626-7689

1 I, Jeffrey L. Berhold, declare as follows:

2 1. I am over the age of eighteen years old and am counsel for non-party
3 Alliance Healthcare Partners LLC (“Alliance”). Unless otherwise indicated, I state
4 the following of my own personal knowledge and, if called upon to do so, I could
5 and would testify competently to the following.

6 2. Pursuant to Civil Local Rules 7-11 and 79-5(f), Alliance submits this
7 declaration in response to defendant Intuitive Surgical, Inc.’s (“Intuitive”)
8 Administrative Motion to Consider Whether Another Party’s Material Should Be
9 Sealed. Alliance seeks to maintain the confidentiality of AHP000527 from its
10 510(k) application for repairing EndoWrists and requests that the Court seal the
11 document itself and redact quotations from it and references to it.

12 3. Alliance filed a 510(k) application with the FDA (K210478) on behalf
13 of non-party Restore Robotics Repairs LLC (“Restore”). The 510(k) application
14 concerns the development, testing, and regulation of proposed methods for
15 repairing EndoWrists. The application was submitted with the understanding based
16 on FDA regulations that the agency would only disclose the 510(k) summary – and
17 only disclose the public summary after clearance. *See* 21 C.F.R. § 20.61(c). The
18 courts of this district and circuit have routinely sealed 510(k) applications because
19 the information in such documents is valuable and its disclosure to competitors
20 would be extremely damaging. *See, e.g., Edwards Lifesciences Corp. v. Meril Life*
21 *Scis. PVT. Ltd.*, No. 19-CV-06593-HSG, 2020 WL 6118533, at *11 (N.D. Cal. Oct.
22 16, 2020), *Lucas v. Breg, Inc.*, No. 15-cv-00258-BASNLS, 2016 WL 5464549, at
23 *2 (S.D. Cal. Sept. 28, 2016) (sealing 510(k) premarket submission to the FDA
24 addressing safety and effectiveness of device).

25 4. Alliance produced the 510(k) application, including correspondence
26 with the FDA, for Attorney’s Eyes Only under a subpoena and protective order in
27 *Restore Robotics, LLC v. Intuitive Surgical, Inc.* (N.D. Fla. 19-cv-55). Alliance
28 later consented to its production by Intuitive in this matter under a similar

1 protective order. Since production in this matter, the FDA has cleared K210478
2 and published the 510(k) summary. After clearance, Alliance conveyed the 510(k)
3 clearance to Restore through the sale of the 510(k) applicant Iconocare Health
4 Solutions. Earlier this year, Restore resolved its dispute with Intuitive.

5 5. Consistent with industry practice, Alliance and Restore have always
6 maintained the 510(k) file within a closely held group of individuals on a need-to-
7 know basis within the companies. Disclosure would give substantial assistance to
8 potential competitors – allowing them to avoid potentially years of time and
9 millions of dollars required to develop their own production and testing methods
10 and regulatory strategy.

11 6. Intuitive has provided notice that it has provisionally filed an eleven-
12 page letter from the FDA to Alliance regarding K210478 (AHP000527) under seal
13 with several motions to exclude testimony of expert witnesses. I represented
14 Alliance and Restore in *Restore Robotics v. Intuitive Surgical* and represent
15 Alliance and Restore regarding the confidentiality of AHP000527. Neither
16 Alliance nor Restore has disclosed AHP000527 to any third party because it would
17 allow competitors to make use of Alliance and Restore’s extensive efforts to
18 commercialize repaired EndoWrists. The letter is part of a dialogue between the
19 applicant and the agency regarding the development, testing, and regulation of
20 proposed methods for repairing EndoWrists. Disclosure would provide competitors
21 with a significant head start in their own efforts.

22 7. Moreover, it would bring significant risk of confusion to the public
23 because the correspondence is far from the final word on the production, testing,
24 and marketing eventually cleared in the application on September 30, 2022. *See,*
25 *e.g., Sarafin v. BioMimetic Therapeutics, Inc.*, No. 3:11-0653, 2013 WL 139521, at
26 *18 (M.D. Tenn. Jan. 10, 2013) (“What is clear, however, is that a deficiency letter
27 is not a final FDA decision, but a request for more information, and, in fact, ‘very
28 few’ PMA are approved without the issuance of a deficiency letter.”). In fact, the

1 FDA has cleared the application and published the 510(k) summary, which governs
2 the clearance.

3
4 I declare under penalty of perjury under the laws of the United States of
5 America that the foregoing is true and correct.

6
7 Executed: March 29, 2023

8 
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
Jeffrey L. Berhold